Supreme Court, U.S.
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No. 03-557

IN THE

Supreme Court of the United States

ST. LOUIS UNIVERSITY,
Petitioner,

v.

AMERICAN CYANAMID COMPANY,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether in this products liability case arising under the court's diversity jurisdiction, the court of appeals properly affirmed the grant of summary judgment in the defendant's favor where the plaintiff—whose sole theory of liability was that the product failed to comply with since-revoked FDA regulations—failed to adduce any evidence of proximate causation sufficient to prove under Missouri tort law that the alleged regulatory violations in fact affected the safety of the product.

PARTIES TO THE PROCEEDING

The only parties to the proceeding are those identified in the petition for writ of certiorari.

RULE 29.6 STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Wyeth is the only publicly held company that owns 10% or more of American Cyanamid Company's stock. Wyeth is the parent corporation of American Cyanamid Company.

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The decision of the court of appeals (Pet. App. 1a-8a) is reported at 336 F.3d 307 (4th Cir. 2003). The decision of the district court (Pet. App. 34a-50a) is reported at 182 F. Supp. 2d 494 (D. Md. 2002).

JURISDICTION

The judgment of the court of appeals was entered on July 16, 2003. Pet App. 1a. The petition for a writ of certiorari was filed on October 10, 2003. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATEMENT OF THE CASE

For more than nine years, St. Louis University ("SLU") has pursued American Cyanamid Company ("American Cyanamid") and several other parties, including the United States, to recover roughly $16 million that SLU paid to sat-

isfy a medical malpractice verdict entered against it by a Missouri state court in 1991. In that case, a jury held SLU liable because its doctors had improperly treated an infection in an infant, Danny Callahan, thus compromising the child's immune system in a way that allowed the live poliovirus contained in his recently administered polio vaccine ("Orimune®") permanently to damage his central nervous system and paralyze him. The Missouri Supreme Court affirmed the verdict against SLU in 1993, holding that the evidence supported the jury's findings both with respect to SLU's negligence and the causal connection between that negligence and the child's injury. *See Callahan* v. *Cardinal Glennon Hosp.*, 863 S.W.2d 852 (Mo. 1993) (en banc).

After SLU paid the judgment in the state court case, it filed state and federal court actions seeking contribution against the federal government and American Cyanamid, respectively.[1] After some procedural wrangling, American Cyanamid brought a declaratory judgment action in the United States District Court for the District of Maryland (where SLU's case against the United States was pending) based on diversity jurisdiction. American Cyanamid sought a declaration that it had no liability to SLU. In response, SLU filed a counterclaim seeking contribution from American Cyanamid under Missouri law.

SLU's claims and counterclaims for contribution against American Cyanamid and the United States were premised on the same contention—that the Orimune administered to Danny Callahan in November 1978 violated the FDA's then-applicable regulations governing the manufacture, testing, and release of oral polio vaccine and that those alleged regulatory violations (if proven) would be sufficient, in and of themselves, to entitle SLU to recover some or all of the $16 million that it had earlier paid to Danny Callahan. SLU re-

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[1] SLU's case against the United States under the Federal Tort Claims Act is the subject of a separate petition for a writ of certiorari filed by SLU. *See St. Louis University* v. *United States*, No. 03-599 (filed Oct. 17, 2003).

lied mainly on the FDA's former regulations governing the "neurovirulence" of the vaccine when tested in monkeys, claiming that various lots of Orimune were made and tested by American Cyanamid and released for use by the FDA in violation thereof. Pet. 3, 4. SLU's legal position was that these regulatory violations were necessarily the proximate cause of Danny Callahan's injury because, had the vaccine not been released, the child would not have received it. *See* Pet. 4 ("[H]ad the regulations been followed, the only vaccine available to Danny would have been the inactive Salk vaccine, which presents *no polio* risk."); Pet. 9-10 ("[H]ad Cyanamid actually complied with the regulations, Orimune would never have reached Danny's lips.... Danny would have been inoculated with an alternative vaccine: the Salk Vaccine.").

The FDA's Former Oral Polio Vaccine Regulations

Oral poliovirus vaccine consists of live, but weakened, strains of poliovirus that stimulate immunity in the recipient by invoking a mild infection. The vaccines were routinely subject to a barrage of tests imposed by FDA regulations that were promulgated in the early 1960s. One such regulation, in effect when Danny Callahan's vaccine was made, required that each batch (or "monopool") of vaccine be tested by injecting a sample into monkeys and then microscopically evaluating their central nervous system tissues for lesions. *See* C.A. App. 103-104. Under the regulations, different dilutions of each monopool were injected into two groups of monkeys. One group was injected intrathalamically (in the thalamus, which is located in the brain), and the second group was injected intraspinally (in the lumbar region of the spine). *See id.* After a period of observation, the monkeys were sacrificed, and a highly trained pathologist conducted a microscopic examination of the tissue taken from the monkeys' brains and spinal cords. *See id.* at 104. The pathologist evaluated the tissue samples for evidence of damage caused by the weakened poliovirus and, pursuant to procedures established by the FDA, assigned a numerical score from 0 to 4 to each sample.

Under the regulations, an identical test was performed on monkeys injected with a "Reference Attenuated Poliovirus," a poliovirus that the FDA chose as a control. *See* C.A. App. 104. The results on each monopool were then compared with the results seen historically on the Reference. Under the regulations, "[t]he virus pool under test is satisfactory for poliovirus vaccine only if . . . a comparative analysis of the test results demonstrate[s] that the neurovirulence of the test virus pool does not exceed that of the Reference Attenuated Poliovirus." *Id.*

In 1991, the FDA amended these regulations and substantially changed the way that monkey neurovirulence tests were to be conducted and evaluated. *See* C.A. App. 111. The FDA made those changes based upon its conclusion, after decades of experience with oral polio vaccine, that there was no correlation between the very small differences in monkey neurovirulence test scores in monopools that had been released and the risk of paralysis in humans:

> No single vaccine lot has been associated with an increased incidence of poliomyelitis. The lots that have been identified as associated with a case of paralytic poliomyelitis have had typically low scores when tested by FDA and the manufacturer for neurovirulence in monkeys.

Id. at 113. The FDA also concluded that "all vaccine previously released or distributed is deemed to meet the requirements of these amended regulations." *Id.* at 116. Then, in 1996, the FDA revoked all of its oral polio vaccine regulations on the express ground that they were "obsolete or no longer necessary to achieve public health goals." *Id.* at 133.

Proceedings Below

On American Cyanamid's motion for summary judgment, the district court held that even assuming the now-revoked FDA regulations set the standard of conduct under state tort law and that a violation had in fact taken place—

SLU failed to present any evidence to establish proximate causation under Missouri law.[2] Pet. App. 44a-47a. The district court explained that, as a matter of Missouri law, SLU could not prevail against American Cyanamid without expert testimony that the alleged violation of the FDA's monkey neurovirulence regulations increased the risk to humans of vaccine-associated paralysis, and that either Danny Callahan's paralysis or its severity resulted from the increased risk allegedly created by that regulatory violation. *Id.* at 45a-47a. Because SLU had failed to submit any evidence in this regard, much less expert testimony, the trial court granted American Cyanamid's summary judgment motion. *Id.* at 46a-47a ("[A]s the absence of any proffered expert testimony by SLU affirms, the results of th[e] [monkey neurovirulence] tests alone are not sufficient to establish a causal connection between a particular individual's contraction of polio, on the one hand, and the marginal difference in neurovirulence between vaccine derived from a seed compliant with the [oral polio vaccine] regulations and vaccine developed from a non-compliant seed, on the other.").[3]

The Fourth Circuit affirmed the grant of summary judgment in favor of American Cyanamid in all respects, holding that "SLU has simply failed to present any competent evidence showing that the defect in the vaccine—excessive neurovirulence—proximately caused Danny's injuries." Pet. App. 5a. The court of appeals explained that even in cases where the violation of a statute or regulation amounts to negligence *per se*, "Missouri law is unambiguous in its requirement that the plaintiff must still prove that the violation proximately caused his injuries." *Id.* at 6a. Thus, because "SLU presented no expert testimony showing that Danny Callahan would not have contracted polio or would have contracted a less severe case of polio had he been given

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[2] It is undisputed that Missouri law applies to this case. *See* Pet. App. 4a, 39a.

[3] In the same opinion, however, the district court held the United States liable in contribution to SLU. Pet. App. 39a-44a.

a vaccine complying with the neurovirulence regulations," summary judgment in favor of American Cyanamid was warranted. *Id.*[4]

In a separate opinion, the court of appeals also reversed the grant of summary judgment against the United States and directed that judgment be entered in the government's favor, holding that, just as the manufacturer of the polio vaccine could not be liable without proof that an alleged regulatory violation actually resulted in a vaccine that was more likely to cause paralysis, neither could the United States be held liable. Pet. App. 18a-27a.

SLU did not seek rehearing or rehearing *en banc* of the summary judgment in favor of American Cyanamid, but it did seek rehearing *en banc* of the decision in favor of the United States. On August 12, 2003, the court of appeals denied SLU's petition, stating that no judge on the court had voted in favor of further review. No. 03-599 Pet. App. 44a.

REASONS FOR DENYING THE PETITION FOR A WRIT OF CERTIORARI

This case is decidedly not worthy of review by this Court. It is a routine products liability case involving the application of garden-variety rules of state tort law. The case is in federal court only because of the parties' diversity of citizenship. There are no substantial questions of federal law (indeed, the FDA regulations at issue were revoked years ago) and no conflicts among the circuits that need to be resolved. The Court should deny the petition.

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[4] In a concurring opinion, Judge Luttig "join[ed] the judgment of the court in this case for the straightforward reason that SLU failed to proffer evidence of proximate causation sufficient to satisfy the Missouri tort standards." Pet. App. 7a. Judge Luttig observed that "SLU proffered no evidence that the vaccine, had it been defect-free, would not have caused Danny Callahan's injuries. As such, SLU failed to create a genuine issue as to that central proximate cause question, without which it cannot survive [American Cyanamid's] summary judgment motion." Pet. App. 7a-8a.

ARGUMENT

I. THE COURT OF APPEALS' DECISION TURNED ENTIRELY ON THE APPLICATION OF MISSOURI TORT LAW AND IS NOT WORTHY OF REVIEW BY THIS COURT.

This diversity case involves only the application of straightforward principles of Missouri products liability law and is thus not worthy of further review by this Court. Indeed, questions of state law are rarely, if ever, reviewed by the Court absent a plain error by the court of appeals. *See Brockett* v. *Spokane Arcades, Inc.*, 472 U.S. 491, 500 & n.9 (1985) (Court "will defer to lower courts on state-law issues unless there is a 'plain' error . . . [or] the lower court is 'clearly wrong' " (internal citations omitted)); *Cort* v. *Ash*, 422 U.S. 66, 73 n.6 (1975) ("[T]his Court must necessarily depend upon the district courts and courts of appeals for initial determinations of questions of state law; indeed, our practice of deference to such determinations should generally render unnecessary review of their decisions in this respect.").

Here, the decision in favor of American Cyanamid by the court of appeals was manifestly correct under Missouri tort law. Missouri law explicitly requires a plaintiff to prove more than the mere existence of a regulatory or statutory violation before liability will be imposed. A regulatory violation would, at most, establish a breach of duty, but it would not suffice to satisfy the separate element of proximate causation.[5] *See Bauman* v. *Conrad*, 342 S.W.2d 284, 287 (Mo. Ct. App. 1961). SLU was still required to come forward with admissible evidence, in the form of expert testimony, that the alleged regulatory violation increased the risk of vac-

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[5] Contrary to SLU's assertion, the district court never made any "factual findings" that American Cyanamid violated the monkey neurovirulence regulations. Pet. 8. The district court, in fact, explained that it "did not find . . . that Orimune was . . . excessively neurovirulent when administered to humans" (Pet. App. 48a) and observed that "[i]f the vaccine lot from which the Orimune administered to [Danny] Callahan itself passed the criteria set by the [oral polio vaccine] regulations, a matter the parties appear to dispute, that would pose an additional obstacle to SLU's proof in this case" (*id.* at 47a n.7).

cine-associated paralysis such that a jury could find that Danny Callahan either would not have become paralyzed at all or would have been paralyzed less severely had he received a vaccine that complied with the then-existing regulations. Pet. App. 5a-6a. The court of appeals held that SLU had no such proof: "SLU presented no expert testimony showing that Danny Callahan would not have contracted polio or would have contracted a less severe form of polio had he been given a vaccine complying with the neurovirulence regulations."[6] *Id.* at 6a. This is exactly what Missouri law requires. *See Nesselrode* v. *Executive Beechcraft, Inc.*, 707 S.W.2d 371, 375-376 (Mo. 1986) (*en banc*) (plaintiff in manufacturing defect case must prove that the defect caused his injuries by proving that had the product been defect-free the injury would not have occurred).

The court of appeals also rejected under Missouri law SLU's argument that the FDA's regulations somehow created a "presumption" that "any vaccine exceeding" the former regulatory standard "posed an unacceptable risk that the recipient would contract polio." Pet. App. 26a. "[S]uch an approach," the court held, "is utterly inconsistent with Missouri law," because it would create automatic liability once a plaintiff has demonstrated a regulatory violation. *Id.* at 27a (citing Missouri cases). The court was, of course, exactly right. As the intermediate court of appeals in Missouri held long ago, "[t]he mere fact that an ordinance has been violated is not sufficient basis for an inference that such violation was the proximate cause of plaintiff's injuries." *Bauman*, 342 S.W.2d at 287. A violation (involving the posted speed limit in that case) "raises *no presumption* that the accident causing the injury was caused by excessive speed." *Id.* at 288 (emphasis added); *see also Bluedorn* v. *Missouri Pac. Ry. Co.*, 25 S.W. 943, 946-947 (Mo. 1894) (*en*

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[6] In the same vein, the court of appeals held that "none of SLU's experts testified that increased [monkey] neurovirulence led to increased incidence of vaccine-associated polio, nor were any qualified to render such an opinion." Pet. App. 5a n.3.

banc) ("[R]ecovery cannot be had upon mere proof of injury and defendant's breach of a statute or ordinance. The plaintiff must prove that the breach of regulation was the proximate cause of his injury."); *Friend* v. *Yokohama Tire Corp.*, 904 S.W.2d 575, 579 (Mo. Ct. App. 1995) ("One of the elements of a negligence per se action is that the violation of the statute was the proximate cause of the injury.")

Any reading of the court of appeals' decision makes clear that the outcome turned solely on Missouri state law; this case thus raises no important questions of federal law, particularly given that the FDA regulations at issue—the only arguably "federal" aspect of this case—are no longer in effect. This case thus should be treated no differently than the ordinary products liability case where final review routinely takes place not in this Court, but in the court of appeals.

II. THE COURT OF APPEALS' DECISION DOES NOT CONFLICT WITH THIS COURT'S OR ANY OTHER CIRCUIT'S DECISIONS, INCLUDING THE FOURTH CIRCUIT'S.

Contrary to SLU's argument, this case presents no deviation from the "binding precedent" in *Berkovitz* v. *United States*, 486 U.S. 531 (1988) (Pet. 12), and it does not conflict in any way with the decisions of any other court of appeals (*id.* at 12-13). The cases upon which SLU relies—*Berkovitz*, *Loge*, and *Baker*—are all inapplicable to the factual and legal issues presented here.

In *Berkovitz*, this Court granted certiorari "to resolve a conflict in the Circuits regarding the effect of the *discretionary function exception* on claims arising from the Government's regulation of polio vaccines." *Berkovitz*, 486 U.S. at 534-535 (emphasis added). The Court never reached the issues of liability (or, more specifically, causation) under state law; indeed, those issues were not even presented. The Court held only that the plaintiffs' claim that the government approved the release of a non-compliant vaccine lot "survives the Government's motion to dismiss" and thus remanded the case for further proceedings. *See id.* at 547-548.

Likewise, the courts of appeals in *Baker* v. *United States*, 817 F.2d 560 (9th Cir. 1987), and *Loge* v. *United States*, 662 F.2d 1268 (8th Cir. 1981), also dealt with the discretionary function exception to the Federal Tort Claims Act; neither reached issues of causation or liability. *Baker*, 817 F.2d at 566 ("Our holding that the plaintiffs' claims are not barred by [the discretionary function exception] does not end the inquiry into whether the Bakers have established a cause of action. Whether the Bakers have a claim against the government depends on whether a private person under like circumstances could be found liable in tort under applicable state law." (footnote omitted)); *Loge*, 662 F.2d at 1275 (reversing grant of motion to dismiss and remanding case for further proceedings).

And contrary to SLU's argument, the court of appeals' opinion in this case certainly does not "flout[] the fundamental doctrine of *stare decisis* by rejecting the binding Fourth Circuit precedent" of *In re Sabin Oral Polio Vaccine Products Liability Litigation*, 984 F.2d 124 (4th Cir. 1993). Pet. 15. Indeed, there is no conflict. The court of appeals' decision in *In re Sabin* dealt solely with claims against the United States and was governed by Florida and Maryland law, not Missouri law. Pet. App. 22a-23a. Whatever the rules of decision may require in Florida and Maryland, Missouri law clearly mandates that proximate cause in a case against a product manufacturer must be established through admissible expert testimony where the issues are, as here, based on science that is unfamiliar to the layperson. *See id.* at 6a, 7a, 25a-26a. Moreover, an intra-circuit conflict ordinarily is not a sufficient basis for granting a writ of certiorari. *See Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957) (*per curiam*) ("It is primarily the task of a Court of Appeals to reconcile its internal difficulties."). This is particularly true where the court of appeals, as it did here, expressly addressed the supposed conflict and had no difficulty distinguishing the authority on which SLU relies. Pet. App. 22a-27a.

III. SLU'S PLEA FOR THIS COURT TO OVERSEE FDA'S REGULATORY FUNCTION IS NOT A VIABLE BASIS FOR GRANTING THE PETITION.

SLU's argument that certiorari in this case "would restore uniformity to the federal vaccine regulations and uphold public confidence in the regulatory system" (Pet. 13) not only fails to provide a viable basis for review by this Court, but it is also frivolous. The FDA expressly changed its regulations in 1991 to preclude the overly technical interpretation advanced by SLU's experts (an interpretation, incidentally, never accepted by the FDA). There was no dispute in the court below, and SLU offered no expert to testify, that any of the vaccine that Danny Callahan received did not completely satisfy all regulatory requirements in place in 1991 and thereafter. Indeed, it was undisputed that the FDA made those changes in 1991 based on its scientific conclusion that the small differences in monkey neurovirulence scores had no correlation to the safety of oral polio vaccine in humans.

Moreover, all of the oral polio vaccine regulations were revoked by the FDA in 1996 on the express ground that they were "obsolete or no longer necessary to achieve public health goals." C.A. App. 133. Further review of this case will do nothing to promote the federal regulatory process or the public's confidence in that process where the process is no longer governed by regulatory standards.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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